AUG - 2 2001

K012085

Thermo Respiratory Group SENSORMEDICS

SomnoStar α Series Sleep System – Summary of Safety and Effectiveness

Submitter:

SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, CA 92887
714-283-2228

Date Prepared:

August 1, 2001

Contact:

Earl Draper

Proprietary Name:

SomnoStar α Series Sleep System

Common Name:

Sleep Analysis System

Classification Name:

Device, Sleep Assessment

Intended Use:

The SomnoStar α Series Sleep System is intended to assist the user in diagnosing patients with sleep disorders by collecting physiological data from a sleeping patient, assisting the user in performing analysis of sleep data, and printing a hard-copy report of these data.

Device Description:

The SomnoStar α Sleep System receive input from bio-physical amplifiers, analyze these data according to software programs designed for use on computer systems included in the system configuration and output data in the form of reports generated by the printer option to the systems. Various components of the systems can be designed into already-existing sleep laboratories. A more detailed description is contained in the Operator's Manual.

Clinical and Non-Clinical Tests of Equivalency:

The SensorMedics SomnoStar α Series Sleep System is equivalent to the SensorMedics 4000 Series Sleep System distributed under 510(k) K915856. The primary difference is the inclusion of a different, optional bio-physical amplifier, the Cephalo Pro, to replace either the AmpStar or Dynagraph II bio-physical amplifiers. Because there are no performance differences caused by using the Cephalo Pro, no additional clinical or non-clinical tests were performed or submitted in the premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2001

Mr. Larry Murdock
Vice President of Marketing
SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K012085
Trade/Device Nam: SomnoStar Alpha Series Sleep System
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: July 2, 2001
Received: July 3, 2001

Dear Mr. Murdock:

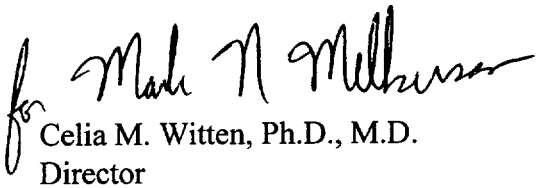
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012085

Device Name: SomnoStar α (Alpha) Series Sleep System

Indications For Use:

The SomnoStar α Series Sleep System is indicated for use to assist the user(s) in diagnosing patients with sleep disorders; by collecting physiological data from a sleeping patient, assisting the user(s) in performing analysis of sleep data and printing a hard copy of these data. The data is collected, staged and scored with a computer-assisted program.

In use, the SomnoStar α Series Sleep System receives input from optional biophysical amplifiers, up to 32 channels in each, which is converted from analog to digital data and stored in a computer storage medium.

The SomnoStar α Series Sleep System is not intended to be used alone or in combination with another product as a life support device, a life support system, or as a critical component to a life support device or system. We do not claim compatibility with diagnostic imaging equipment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milkins

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012085

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)